

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on November 22, 2006, and the references cited therewith. Claims 2, 3, 8-10, 15-16, 34, 42, 45, 46, and 49 are amended, claims 1, 4-7, 11-14, 17-33, 35-41, 43-44, 47 and 51 are canceled, and claims 52-58 are added; as a result, claims 2-3, 8-10, 15-16, 34, 42, 45-46, 48-50 and 52-58 are now pending in this application. No new matter has been added.

'103 Rejection of the Claims

In reference to item 1 of the Office Action dated 11/22/2006, claim 51 is rejected under 35 USC ' 103(a) as being unpatentable over Japanese Kokai 3-57629 in view of Japanese Kokai 58-153,326. Applicant traverses the rejection. Applicant has cancelled claim 51 and therefore this rejection is moot.

In reference to item 2 of the Office Action dated 11/22/2006, claims 1-3 and 42 are rejected under 35 USC 103(a) as being unpatentable over Kumakura et al (5,061,057) in view of the '629 reference and the '326 reference. Applicant traverses the rejection.

Applicant has cancelled claim 1. Claims 2-3 and 42 as amended depend from independent claim 46. Therefore Applicant will discuss the patentability of claim 46 in light of the references cited.

Kumakura teaches hard and soft contact lenses and methods of making the same. The lens in Kumakura is made to be removably positioned on the surface of the cornea and held in position on the eye by tension not by surgical insertion into the cornea of the eye as a corneal implant. Applicant's specification at page 3 lines 13-15 clearly disclose that insertion of the optical device into the cornea is for example as disclosed by Choyce in patent 4,655,774 ('774). In '774, figures 3b, 5, and 6b clearly show placement of the optical device as intra-corneal (i.e. not topical to the cornea). Therefore, Kumakura teaches away from a method of making an optical device suitable for insertion into the cornea of the eye as Kumakura teaches a contact lens removable by the wearer and a method of making the same.

Further Kumakura fails to teach a method of making pores within the optical device with dimensions large enough to permit the ingrowth of corneal tissue. If the lens of Kumakura were

suitable for ingrowth of corneal tissue, the contact lens would become affixed to the surface of the cornea. Removal of the contact lens, as required for contact-lens maintenance and lasting performance, would do damage to the eye and would make the lens produced by the method of Kumakura unfit for its intended purpose, a removable contact lens.

The '629 reference does not make up the deficiency of Kumakura as the '629 reference teaches an IOL that is likewise not suitable for insertion into the cornea of the eye. First the '629 reference fails to teach an optical device for insertion into the cornea of the eye as a corneal implant. Instead, the '629 reference teaches an IOL device which is suitable for insertion into the posterior chamber of the eye behind the iris. IOLs are inserted into and operate from the interior chamber of the eye and are never intended to contact the cornea. In fact, IOL contact with the posterior surface of the cornea is well-known to damage corneal tissue, and IOL surface modifications are sought to reduce the adhesion of corneal tissue in the event of incidental or unintentional contact. See, for instance, US Patent No. 5171267, col. 7, lines 36-65. Therefore, the '629 reference not only does not teach this element but it in fact teaches away from Applicant's invention as the method disclosed in the '629 reference would never produce an optical device suitable for insertion into the cornea of an eye as a corneal implant.

Further still, the '326 reference does not make up the deficiencies of either Kumakura or the '629 reference as the '326 reference only discloses the use of a mask in the etching of a film on a wafer of a semiconductor which is not even in the same art as ophthalmic devices.

Applicant respectfully asserts that the Examiner has failed to make a *prima facie* case of obviousness for claims 46, 2-3, and 42 as there is no suggestion, motivation or teaching for making the combination of references in the manner made by the Examiner except for hindsight reconstruction in light of Applicant's own disclosure.

Therefore independent claim 46 is patentable over Kumakura, the '629 reference and the '326 reference either alone or in combination.

Claims 2-3 and 42 depend from claim 46 and are patentable for at least the reasons cited in support of claim 46.

In reference to item 3 of the Office Action dated 11/22/2006, claims 45, 8-10, 15, 16, 34, 49 and 50 are rejected under 35 USC 103(a) as being unpatentable over Kumakura et al in view

of the '629 reference, the '326 reference and Freeman et al (5,331,132). Applicant traverses the rejection.

First, claims 45, 8-10, 15, 16, and 34 depend from claim 1 and are therefore patentable for the reasons cited in support of claim 1.

Second, the distinct design criteria of a corneal implant are different from those of either an IOL or a contact lens and therefore must also be considered when comparing the art of the subject matter of claims 45, 8-10, 15, 16, 34, and 49-50. While the Examiner rejects these claims as unpatentable in view Freeman, anyone with ordinary skill in the art would realize that the method of Freeman, without extensive process modification that are not taught, would make the corneal implant of Applicant's invention defective for its intended purpose. Because the process of Freeman creates a plume of ablated material above the polymer work piece, the process of Freeman is not clean enough for the fabrication of a corneal implant. As is well known in the field of polymer microprocessing and is discussed in several articles (eg, W. Spiess and H. Strack, "Structuring of polyimide by ArF excimer laser ablation," *Semicond. Sci. Technol.* **4**, 486-490 (1989)), laser ablation of polymers leaves a residue of micron-scale particulates on the work piece. The process of Freeman is therefore insufficient for the level of cleanliness required in the fabrication of a corneal implant.

The process described in Claim 45 is based on a radiation induced chemical reaction that necessarily does not leave a particulate residue as does the ablation process of Freeman. In particular, the chemical reaction of a polymer film to ion-beam irradiation has been analyzed in R. Kallweit, et. al., "Correlation between chemical modification and generated refractive index on ion implanted PMMA," in *Materials Modification by Energetic Atoms and Ions*, Mat. Res. Soc. Symp. Proc. **268**, 363-8 (1992).

Neither is Freeman applicable to the subject matter of Claim 16, which describes a *reflective* diffraction grating. The method of Freeman can produce only *transmissive* diffractive structures, which have fundamentally different optical properties and cannot achieve the optical effect of the reflective grating described in Claim 16. In particular, the process described in Claim 16 and illustrated in Figs. 9-10 of the specification produces a diffraction grating with modulation or variation approximately normal or perpendicular to the plane of the film, whereas

the method of Freeman can produce modulation or variation only approximately parallel to the plane of the film. The '629 reference and the '326 reference do not make up these deficiencies.

Independent claim 49 is patentable over Kumakura, the '629 reference, and the '326 reference for the reasons cited in support of claim 46. Further Freeman fails to remedy the deficiencies of the Kumakura, the '629 reference, and the '326 reference either alone or in combination. Therefore claim 49 is patentable over Kumakura, the '629 reference, the '326 reference and Freeman either alone or in combination.

In reference to item 4 of the Office Action dated 11/22/2006, claims 46 and 47 are rejected under 35 USC 103(a) as being unpatentable over Poler (4,450,593) in view of Kumakura et al. Applicant traverses the rejection

The method of making the lens in Kumakura does not teach making pores suitable for ingrowth of corneal tissue. If the lens of Kumakura were suitable for ingrowth of corneal tissue, the contact lens would be affixed to the surface of the cornea. Removal of the contact lens, as required for contact-lens maintenance and lasting performance, would do damage to the cornea and make the lens produced by the method of Kumakura unfit for its intended purpose, a removable contact lens.

Poler fails to remedy the deficiency of Kumakura. Poler teaches both an IOL and a contact lens. The Examiner makes an incorrect statement that

"Clearly, in making an IOL, it would be advantageous to allow for corneal ingrowth so that the lens would be more securely anchored in place."

The Examiner provides no support for this bold statement. To the contrary, it is widely recognized in the field of ophthalmology, and described for instance in US Patent No. 5,375,611 at column 1 lines 48-53, cellular proliferation on an IOL is associated with capsular opacification, which is commonly referred to as "secondary cataracts," an extremely undesirable complication. Much of the current research on improved IOLs therefore seeks surface modifications to *discourage* any sort of cellular adhesion, proliferation, or ingrowth.

The references either alone or in combination fail to teach each element of the claim and therefore the Examiner has failed to establish a prima facie case of obviousness. Therefore claims 46 is patentable over Kumakura and Poler either alone or in combination.

Claim 47 has been cancelled.

In reference to item 5 of the Office Action dated 11/22/2006, claim 48 is rejected under 35 USC 103(a) as being unpatentable over Kumakura in view of Freeman et al. Applicant traverses the rejection.

Claim 48 depends from claim 46 and is patentable for the reasons cited in support of claim 46. Further, the combination of elements found in claim 48 are not taught or suggested by the combination of Kumakura and Freeman for the reasons stated in response to item 3 of the Office Action. Further still, the method in Freeman is unfit for our intended purpose of the fabrication of a corneal implant which must necessarily be biocompatible.

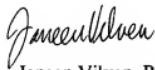
Therefore, claim 48 is patentable over Kumakura and Freeman either alone or in combination.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (505 998 6134) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-4213

Respectfully submitted,



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